

INJECTION DEVICE

The invention concerns an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

An injection device of this kind is known from DE 42 23 958 A1.

5 The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

It is therefore an object of the invention to make a new injection device available.

10 This object is achieved in one manner by the subject matter of Claim 1. As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the 15 plunger, which then moves independently of the container.

The stated object is achieved in a different manner by the subject matter of Claim 6.

An injection device of this kind has a simple configuration and operates very 20 reliably and comfortably for the patient.

The stated object is achieved in a different manner by the subject matter of Claim 36.

An injection device of this kind combines high precision with simple operation and compact design.

25 Other ways of achieving the stated object are evident from the subject matters of Claims 44 and 46. The principle of Claim 44 is highly suitable for injection devices with an automatic injection sequence, and the principle recited in Claim 46 is particularly "foolproof" when a used cartridge needs to be replaced with a 30 new one.

The stated object is achieved in another manner by the subject matter of Claim 51.

Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

5 In this context, it is particularly advantageous to proceed in accordance with Claim 52.

10 The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

15 Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings - which are in no way to be understood as a limitation of the invention - and from the dependent claims.

In the drawings:

20 FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

25 FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

30 FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

35 FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

5 FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

10 FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

15 FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

10 FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

15 FIG. 10 shows a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

20 FIG. 11 shows a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

25 FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 shows a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

5 FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

10 FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 shows a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

15 FIG. 20 shows a section viewed along line XX-XX of FIG. 19;

FIG. 21 shows a section viewed along line XXI-XXI of FIG. 19;

20 FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds to the position of FIG. 2;

FIG. 23 shows a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

25 FIG. 24 shows a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 shows a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

5 FIG. 26 shows a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

10 FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

15 FIG. 31 is a depiction showing how a new cartridge is introduced into cartridge holder 80;

FIG. 32 is a depiction showing how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

20 FIG. 33 is a depiction showing the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

25 FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

30 FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

5 "Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

10 FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2.

(In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted.

15 Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

20 Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid 53 to be injected (FIG. 4) and is equipped with at least 25 one viewing window 54 through which the fill level of cartridge 52 can be observed.

25 Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.

Located at the proximal end of injection device 30, for cocking, is a cocking cap 56 that is screwed with its external thread 58 into a corresponding internal thread 60 (FIG. 2) of proximal barrel part 50, in order to cock the injection device prior to an injection. As described later with reference to FIGS. 16 and 17, cocking of injection device 30 is possible only if a needle 76 is installed. In the position as shown in FIG. 1, injection device 30 is therefore cocked, since a needle 76 is installed and cocking cap 56 has been screwed all the way into proximal barrel part 50. In this context, a resilient latching peg 64 is located at the distal end of elongated latch opening 38 (cf. FIG. 3). In this position setting knob 32 is "in neutral," i.e. it can be rotated in the direction of arrow 34 (FIG. 1) without setting a dose. Dose setting is thus deactivated in this context.

FIG. 2 shows injection device 30 after cocking and after cocking cap 56 has been unscrewed. The latter is unscrewed before an injection in order to prepare the device for an injection. In response to the action of a cocking spring 172 (FIG. 7), latching peg 64 moves slightly in the proximal direction and comes to rest against the proximal edge of longitudinal latch opening 38 (cf. FIG. 2). In this position - before an injection - a desired injection dose can be set by rotating setting knob 32.

To read off the dose, magnifier 42 has two individual magnifiers 70, 72. Because of the large number of dose settings that are possible for an injection - in the present case, for example, thirty different settings between "0" and "58" units - the scale is printed in two rows on circumferential surface 69 (FIGS. 9 and 11) of dose-setting knob 32. FIG. 2A shows a development 69' of said circumferential surface 69. The scale has a first row 71 with the numbers "0", "4", "8", etc. and a second row with the numbers "2", "6", "10", "14", etc. A stop 75 marks the zero position. Lens 70 shows a number from first row 71 in magnified fashion, and lens 72 shows a number from second row 73 in magnified fashion (cf. FIG. 2). This makes possible an unequivocal readout, i.e. in FIG. 2 the dose that is set is 16 units. (In the present example, the dose can always be displaced by two units, i.e. can be set from "0", "2", "4", etc. units to "58" units.)

In the position as shown in FIG. 2, triggering of injection device 30 is possible. This is done by pressing on clip 40 in the direction of a force vector 74 (FIG. 1). Latching peg 64 is thereby pressed radially inward by radially inwardly projecting protrusion 44. Cocking spring 172 (FIG. 7) then causes first an insertion of injection needle 76 (FIG. 4) and then an injection, through the inserted needle 76, of the injection dose that was set. This is described below with reference to FIGS. 24 and 25. This is therefore a device comprising a hidden needle 76, i.e. the latter is not visible to the patient, and the injection operation proceeds automatically after triggering.

Device 30 is thus cocked by screwing in cocking cap 56, and by unscrewing cocking cap 56 is brought into the position as shown in FIG. 2, in

which the desired dose can be set and then injected.

FIG. 3 shows injection device 30 in the position as shown in FIG. 1, the proximal region being depicted cut away. Cartridge 52, with fluid 53 contained in it, is visible. Cartridge 52 is located in a cartridge holder 80 that has at its proximal end a tapered neck 82 and is equipped there with an external thread 84. Cartridge 52 projects with its neck 86 into this neck 82. It is equipped at its proximal end with a rubber membrane 88 that is perforated, during use, by distal part 90 of needle 76. Needle 76, 90 is mounted on a usual needle holder 92 that is screwed, with its internal thread, onto external thread 84 of cartridge holder 80. In the cocked state it is protected by cocking cap 56 and is then not visible.

As FIG. 3 clearly shows, cocking cap 56 rests with a cylindrical segment 56A against needle holder 92, and biases the latter in the distal direction. Latching knob 64 thereby moves into its distal position in recess 38, as depicted in FIGS. 1 and 3, and setting knob 32 is deactivated as already described.

If the patient has forgotten to screw on a needle 76, needle holder 92 is absent and device 30 cannot be cocked, because cylindrical segment 56A of cocking cap 56 now projects into cavity 98 of cartridge holder 80, as shown in FIG. 16. Latching knob 64 is then in the position as shown in FIG. 17, which in FIG. 3 is labeled 64', i.e. in this state cocking and injection are not possible. This ensures that without needle 76, injection device 30 cannot be cocked.

FIG. 4 shows injection device 30 in the state after an injection. Needle 76 projects out of proximal barrel part 50. Cartridge holder 80 has an annular collar 100, and this rests against a damping ring 102 that is braced against an annular shoulder 104 on the inner side of proximal barrel part 50. This is the proximal end position of cartridge holder 80.

Located in cartridge 52, in the usual way, is a rubber piston 106, and during an injection (after the insertion of needle 76), the latter is displaced by a plunger 108 in the proximal direction in order to expel from cartridge 52 the quantity of fluid previously set with setting knob 32.

FIG. 5 depicts, in exploded and three-dimensional fashion, the various parts of the proximal segment of injection device 30. Provided in proximal barrel part 50 is internal thread 60 into which external thread 58 of cocking cap 56 can be screwed in order to cock the injection device. This is a coarse thread with a trapezoidal thread cross section.

Middle barrel part 48 has at its proximal end an external thread 109 that serves to connect with an internal thread 110 at the distal end of

proximal barrel part 50. Middle barrel part 48 also has, at its proximal end on the inner side, short axial splines 112 that provide longitudinal guidance for a longitudinal rib 111 (or multiple longitudinal ribs) on the outer side of cartridge holder 80. These longitudinal ribs 111 prevent cartridge holder 5 80 from rotating as long as injection device 30 is in its ready-to-operate state. This longitudinal guidance is deactivated during replacement of a cartridge 52, i.e. longitudinal ribs 111 then slide out of axial splines 112 (cf. FIGS. 26 through 32 below). The longitudinal guidance provided by parts 10 111, 112 prevents cartridge holder 80 from rotating relative to barrel part 50 while an injection needle 76 is being replaced, and thereby detaching from a front adapter part 116 (FIGS. 6 and 14).

Cartridge holder 80 has at its distal end an external thread 114 that serves to connect with an internal thread 115 (FIGS. 6 and 14) of front adapter part 116. External thread 114 has an interruption 118 which has a 15 specific function in the context of cartridge replacement. This is described below.

Neck 82 of cartridge holder 80 is configured in the manner of a socket wrench, and for that purpose has a diagonally extending groove 120 that makes possible a rotation of adapter part 116 (cf. FIG. 6) when said neck 82 is inserted into adapter part 116, which is of correspondingly complementary configuration so that it can engage into groove 120 (cf. FIGS. 14 and 20). Parts 120 and 226 thus fit into one another like a key and lock.

Needle 76 and cartridge 52 are not depicted in FIG. 5 so as not to overload the depiction with too many details.

FIGS. 6 through 9 depict, in exploded and three-dimensional fashion, the remaining parts of injection device 30. The depiction is in some cases highly schematized in order to facilitate comprehension of the invention. FIG. 9 is depicted at an enlarged scale as compared to FIGS. 6 and 7, for better depiction of details.

30 In FIG. 6, front adapter part 116 with its internal thread 115 is followed by a rear adapter part 122 that, during assembly, is joined rotatably but axially nondisplaceably to the front (proximal) adapter part 116, a torque-dependent coupling (K7 in FIG. 18) being provided between parts 116 and 122.

35 Next comes a guide part 124 that provides axial guidance of plunger 108 (FIGS. 7 and 8) and that during assembly is joined nonrotatably but axially displaceably to rear adapter part 122. This is followed by a stop ring 126 whose function will be explained below and which is installed in an annular groove 262 of rear adapter part 122.

40 Distal barrel part 36 receives an internal tube 130 in the rotational

position depicted in FIG. 6, i.e. a longitudinal slot 136 of internal tube 130 aligns with latch cutout 38 of barrel part 36. Internal tube 130 forms, over a short portion of its longitudinal extension, the annular part 46 that is visible in FIG. 1 and has as rotation preventer a protrusion 133 that projects 5 into a corresponding aperture 133' of barrel part 36. At its proximal end, internal tube 130 is equipped with an external thread 132 that serves to connect with an internal thread 139 (FIG. 5) at the distal end of middle barrel part 48. Internal tube 130 is equipped over a portion of its length 10 with internal axial splines 134. Its axial longitudinal groove 136 provides longitudinal guidance for latching member 64 so that the latter cannot rotate in barrel 36. Internal tube 130 furthermore has, in the region of its distal end, two lateral latch cutouts 138, 140 for latching with corresponding barbs 142 on a molded part 144 (depicted in FIGS. 9 and 10) that carries, inter alia, clip 40.

15 FIG. 7 shows, on the right next to distal barrel part 36, front part 148 and rear part 150 of a so-called setting sleeve 151 that serves for dose setting, i.e. as a setting member. Upon assembly, parts 148 and 150 are immovably joined to one another by latching and then form setting sleeve 151. The latter is rotated during dose setting and thereby displaces plunger 108, 20 which in the assembled state engages with its external thread 159 into internal thread 152 of part 148, in the proximal direction.

25 Part 148 guides, in an annular groove 153, a support part 155 which carries latching peg 64 and is pressed radially outward by a compression spring 157 (cf. FIG. 7).

30 FIG. 8 shows plunger 108 at enlarged scale. Its external thread 159 is a rectangular coarse thread. Plunger 108 has two longitudinal grooves 156, 158. In the assembled state, a protrusion 160 (FIG. 6) of guide part 124, serving as an engagement member, engages into longitudinal groove 156, thereby preventing any rotation of plunger 108 relative to the barrel of injection device 30 during dose setting and injection.

35 As depicted, a micro-tooth set 162 somewhat like that of a toothed rack is present in longitudinal groove 158. Tooth set 162 extends from proximal end 164 approximately as far as a stop 166 in groove 158, in this case over approximately two-thirds of the longitudinal extent of plunger 108. In the region of its distal end 168, plunger 108 is equipped with an annular groove 170 which serves as latching element and which has, during replacement of a cartridge 52, a function that will be explained in more detail below with reference to FIG. 29.

40 In FIG. 7, 172 designates the cocking spring which stores the energy for an injection and, in the assembled state, is braced at its proximal end 174 via a plain washer 176 against part 148, and biases the latter in the proximal direction.

With its distal end 178, spring 172 is braced against an annular

shoulder 180 of molded part 144 (FIG. 9). The latter is made of a flexible plastic and has a resilient latching element 182 comprising a latch protrusion 184 that, during dose setting, engages into splines 220 (FIG. 7) of part 148 and causes clicking sounds upon rotation of part 148. These sounds allow blind patients to set the desired dose by counting the clicks. In addition, after dose setting latch protrusion 184 immobilizes part 148 in its set position by engagement into splines 220, i.e. acts like a coupling (K3 in FIG. 18) that is disengaged in the course of an injection.

Magnifier 42 is shown only schematically in FIG. 9. It is introduced from below into a cutout 186 of molded part 144. This is symbolically indicated by a dot-dash line 188.

A return spring for setting knob 32 is labeled 190 in FIG. 9. It is a torsion spring. Its distal end 192 is nonrotatably joined to setting knob 32, and its proximal end 194 to molded part 144. After an injection, this spring 190 rotates setting knob 32 back into its zero position, in which a dose of "0" can be read off through magnifier 42.

Setting knob 32 has on its inner side splines 196 which interact with corresponding splines 198 of part 150 of setting sleeve 151. (FIG. 9 is drawn at a larger scale than FIG. 7.) An opening 199 (FIG. 11) at the distal end of setting knob 32 is closed off by a cover 200 (FIGS. 9 and 35).

FIG. 10 shows molded part 144 in longitudinal section. Its right-hand part 202 is located practically entirely in the interior of distal barrel part 36. The latter has a lateral aperture 204 (FIG. 7), and through this, clip 40 projects outward and prevents molded part 144 from rotating. Longitudinal ribs 203 provide low-friction lateral guidance for spring 172, which is depicted in FIG. 7.

FIG. 11 shows setting knob 32 in longitudinal section. Its internal splines 196 extend over approximately two-thirds of the total length of this part. The latter thus has, at the distal end, a short region 206 that has no splines, and has a longer proximal region 208 where splines also are not present. On its outer side, setting knob 32 has an annular ridge 210 for engagement into a corresponding annular groove 212 (FIG. 6) of distal barrel part 36. It is clipped into this annular groove 212 during assembly. It also has an annular space 211 which receives return spring 190 that is depicted in FIG. 9.

FIG. 12 shows part 150 of setting sleeve 151. The latter has at the proximal end two radially resilient hooks 212 (FIG. 7) for positive engagement into corresponding cutouts 214 of part 148 of the setting sleeve. This engagement is symbolized in FIG. 13 by a dot-dash line 216.

As is clearly evident from FIGS. 11 and 12, outer splines 198 of part 150 are configured for positive engagement into inner splines 196 of setting knob 32. When outer splines 198 are in engagement with inner splines 196, part 150 - and with it part 148 - can then be rotated by turning setting knob 32,

i.e. it is possible to set a dose.

When outer splines 198 are located in region 206, setting knob 32 then cannot transfer any torque to part 150. This is the free-wheeling neutral position of setting knob 32, which was explained in detail with reference to FIGS. 1 and 3.

When outer splines 198 are located in region 208, setting knob 32 also cannot transfer any torque to part 150. This is the position after an injection; in this position, setting knob 32 is turned back into its zero position by return spring 190 (FIG. 9) so that the next dose setting operation can begin again at the "0" position.

As FIG. 13 shows particularly clearly, part 148 has at its distal end external splines 220 that, when device 30 is in the cocked state, interact with latch protrusion 184 (FIG. 10) in order to generate clicking sounds during dose setting and to "immobilize" a dose once it has been set, i.e. to prevent inadvertent resetting of that dose.

Part 148 furthermore has external splines 222 at its proximal end. When the device is in the cocked state, these splines 222 are not in engagement with internal splines 134 of internal tube 130 (FIG. 6), so that parts 148 and 150, which together form setting sleeve 151, are freely rotatable so that the dose can be set. This state is depicted in enlarged fashion in FIG. 17 (coupling K4 open; alternatively, in FIG. 17 coupling K4 could also be closed in order to block any rotation of setting sleeve 151 by the patient).

During an injection, part 148 (together with part 150) is moved in the proximal direction, and its splines 222 thus come into engagement with internal splines 134 of internal tube 130 (indicated only schematically in FIG. 13). This situation is depicted, for example, in FIG. 24 (coupling K4 closed).

As soon as axial internal splines 134 engage into external splines 222, setting sleeve 151 is prevented from rotating relative to internal tube 130, i.e. the injection dose that has been set cannot change during the injection operation. The tooth count of splines 220 equals the tooth count of splines 222. In the present exemplary embodiment, this count is thirty-two teeth each to allow a total of thirty dose settings from 0 to 58 units (cf. FIG. 2A and FIG. 36). (Two teeth are not used for dose setting; cf. FIG. 36 and its accompanying explanations.)

FIG. 14 shows front adapter part 116 and rear adapter part 122 in

exploded fashion, at enlarged scale, and in a three-dimensional depiction. Front adapter part 116 has a cutout 224 with protrusions 226 which together serve to connect to diagonal groove 120 (already explained; FIG. 5) of cartridge holder 80 in order to make possible, by means of the (rotated) 5 cartridge holder 80, a rotation of front adapter part 116. Such rotation can become necessary in unfavorable circumstances during cartridge replacement.

Front adapter part 116 furthermore has two axial plastic springs 228 which, as shown in FIG. 15, in the assembled state rest against cartridge 52 and apply to it a force in the proximal direction (cf. also FIG. 20).

Front adapter part 116 furthermore has a resilient tongue 230 which extends in the axial direction and on whose free end, on the radially inner side, is provided a latching member 232 (with a triangular cross section) that interacts with corresponding latch protrusions 234 of rear adapter part 122 and forms with them a slip coupling that becomes effective during cartridge 15 replacement and prevents the patient, when screwing cartridge holder 80 onto front adapter part 116, from exerting too much torque on front adapter part 116 and thereby damaging it. Specifically, if too high a torque is exerted by the patient in the direction of arrow 236 (FIG. 14), latching member 232 then slips over latch protrusions 234 and front adapter part 116 rotates relative to rear adapter part 122, so that the injection device cannot be damaged.

During assembly, the two adapter parts 116, 122 are releasably latched to one another by the fact that an annular ridge 238 of front adapter part 116 is snapped into an annular groove 240 of rear adapter part 122, as shown by FIG. 15. Annular groove 240 is located on two axial protrusions 252, 254.

Front adapter part 116 also has a radially inwardly projecting resilient latching member 242 that serves to snap into cutout 118 (FIG. 5) of outer thread 114 provided on cartridge holder 80. After a cartridge replacement, latching member 242 snaps into this cutout 118. When an old cartridge 52 is to be removed, front adapter part 116 is first rotated along by the rotation of cartridge holder 80 in the direction of an arrow 237 (FIG. 14), since latching member 242 causes a torque to be transferred from cartridge holder 80 to adapter part 116. This rotational movement serves to reset plunger 108, as will be described below with reference to FIGS. 27 through 29. Only when plunger 108 has been completely reset, i.e. moved in the distal direction to a 30 stop (K2 in FIG. 29), does latching member 242 snap out of cutout 118, and cartridge holder 80 is unscrewed from front adapter part 116 so that cartridge 52 can be exchanged. This ensures that during a cartridge replacement, plunger 108 is automatically moved in the distal direction to a stop (K2 in FIG. 29). Plunger 108 is then releasably latched in this position by a latching member 35 40 320 (cf. FIGS. 28 and 29).

As FIG. 14 shows, ratchet teeth 234 are located on a tubular segment 246 of rear adapter part 122. This segment 246 has on its proximal region a radially resilient segment 248 that is equipped on its radially inward side

with ratchet teeth 250. These serve to engage into micro-tooth set 162 depicted in FIG. 8, and ratchet teeth 250 are therefore configured in substantially complementary fashion to micro-tooth set 162 (cf. FIG. 15). They form a slip coupling with the latter, i.e. when a displacement force exceeding a defined magnitude occurs between ratchet teeth 250 and micro-tooth set 162, ratchet teeth 250 slip over the teeth of micro-tooth set 162. Such is the case in the final phase of an injection and upon replacement of a cartridge, since in that context plunger 108 must be reset into its distal end position (cf. FIGS. 27, 28, and 29).

Axial protrusions 252, 254 extend in the proximal direction, and their purposes include continuously maintaining a predefined clearance between front adapter part 116 and rear adapter part 122, and rotatably mounting front adapter part 116. The radially outer side of rear adapter part 122 is equipped with external splines 256 which are configured in complementary fashion to internal splines 134 of internal tube 130 and engage into them as long as adapter part 122 is located in internal tube 130.

As FIGS. 14 and 15 show, rear adapter 122 also has on its distal end a tubular extension 260 that is equipped in its distal end region with an annular groove 262 which receives stop ring 126 depicted in FIG. 6. As shown in FIG. 15, tubular extension 260 has an axially extending orifice 264 through which protrusion 160 (cf. FIG. 6) of guide part 124 projects into the one longitudinal groove 156 of plunger 108 and thereby joins the latter nonrotatably, but axially displaceably, to guide part 124.

As shown in FIG. 6, guide part 124 has two axial protrusions 266, 268 which lie diametrically opposite one another and project in the proximal direction. Because of annular ridge 238 (FIG. 14) on front adapter part 116, the inside diameter of protrusions 266, 268 increases in their proximal region 266', 268'. Protrusions 266, 268 are axially guided by two guide openings 272, 270, approximately complementary to them, of rear adapter part 122, i.e. between adapter part 122 and guide part 124 a relative rotational movement is not possible, but an axial displacement is. The latter is limited in the one direction by stop ring 126 (cf. FIG. 15) and in the other direction by contact of axial protrusions 266, 268 against front adapter part 116 (cf. FIG. 25) or by contact of guide part 124 against rear adapter part 122. Guide part 124 is equipped on its periphery with external splines 274 which, during an injection, are guided in internal splines 134 of internal tube 130. Since guide part 124 is joined nonrotatably to adapter part 122 and to plunger 108, the rotational position of these parts is determined by the rotational position of guide part 124.

When injections take place, guide part 124 is always joined nonrotatably, but axially displaceably, to internal tube 130. Upon replacement of a cartridge this nonrotatable connection is disengaged (cf. FIGS. 26-32), and guide part 124, as well as parts 108 and 122 nonrotatably joined to it, 5 can then rotate relative to barrel 36, while setting sleeve 151 is in engagement by way of its external splines 222 with internal tube 130 and therefore cannot be rotated. Simple resetting of plunger 108 is thereby possible, as will be described below.

On its distal side, guide part 124 has a tubular extension 276 on whose 10 outer side (as shown in FIG. 15) an annular groove 278 is provided.

As shown in FIG. 7, proximal part 148 of setting sleeve 151 is equipped on its proximal side with a cutout 280 on which four radially inwardly projecting latching segments 282 are provided; upon assembly, these are 15 clipped into annular groove 278 of guide part 124 and thereby join setting sleeve 151 rotatably, but axially nondisplaceably, to guide part 124.

Since part 148 of setting sleeve 151 is in engagement by way of its internal thread 152 with external thread 159 of plunger 108, and since the latter is prevented from rotating by protrusion 160 of guide part 124, a rotation of parts 150, 148 causes an axial displacement of plunger 108, of the two adapter parts 116, 122 joined to it via teeth 250 (FIG. 14), and thus also of cartridge holder 80; in other words, as a dose is set, all these parts are displaced together over a distance that corresponds to the desired dose setting. This will be explained in more detail below with reference to FIG. 23.

FIGS. 16 and 17 show what happens when the patient attempts to cock injection device 30 in the absence of a needle. In this situation, proximal opening 98 of cartridge holder 80 is not covered by needle holder 92 (FIG. 3), and part 56A of cocking knob 56 projects through said opening 98 and rests 30 against the proximal end of cartridge 52. As FIG. 17 shows, in this case latching peg 64 is not moved far enough in the distal direction that it can snap into latch opening 38, i.e. it is not possible to cock the device.

In this situation, in the position as shown in FIG. 16 it is theoretically possible to set a dose, since setting knob 32 is in engagement with dose-setting sleeve 151; but because no needle is present, fluid 58 in cartridge 52 acts like a rigid body which presents to any displacement of plunger 108 a resistance that cannot be overcome, thus preventing any such displacement. Dose setting in this position is therefore prevented, and after 35 cocking cap 56 is unscrewed, device 30 returns to its uncocked position as shown in FIG. 4, so that the patient is forced to screw on a needle 76 so that 40 he or she can cock device 30, then set a dose, and then inject.

The present invention makes use of the interaction of various coupling elements, partly in the form of position-dependent couplings and partly in the form of force-dependent couplings, and of a coupling that couples two elements nonrotatably to one another but allows an axial displacement between them.

5 FIG. 18 shows these couplings in a schematic overview.

Between external splines 198 (FIG. 12) of setting sleeve 151 and internal splines 196 (FIG. 11) of setting knob 32, there exists a position-dependent coupling K1 whose mode of operation has already been described. It makes possible automatic resetting of setting knob 72 to "0" during an 10 injection, and it deactivates setting knob 32 when the device is in its cocked position of FIG. 3.

15 A force- and position-dependent latching coupling K2 is provided between the distal end of plunger 108 and the distal end of setting sleeve 151. This coupling K2 is described in more detail below with reference to FIGS. 28 and 29. It has a function in the context of replacement of cartridge 52.

A force- and position-dependent latching coupling K3 is provided between barrel-mounted latching member 184 and external splines 220 of setting sleeve 151. This coupling K3 is engaged when the device is in its cocked position, and serves to store the desired dose setting. K3 is opened during an injection, but the stored information cannot be lost because the function of coupling K3 is seamlessly taken over by a coupling K4. (In order to facilitate comprehension, in FIG. 18 latching member 184 is merely indicated with dot-dash lines.)

Coupling K4 is a position-dependent coupling, and is provided between external splines 222 at the proximal end of setting sleeve 151 and internal splines 134 of internal tube 130. Coupling K4 is open as long as injection device 30 is in its cocked position, so that setting sleeve 151 can be rotated there in order to set a dose.

30 Directly after the beginning of an injection and during the entire course of an injection, coupling K4 is closed (cf. FIG. 15), i.e. setting sleeve 151 is then guided nonrotatably but axially displaceably in internal tube 30. Coupling K4 is also closed when a cartridge 52 is being replaced.

35 A position-dependent coupling K5 is provided between external splines 274 of guide part 124 and internal splines 134 of internal tube 130, and also between external splines 256 of rear adapter part 122 and internal splines 134. This coupling K5 is always closed as long as the device is ready for injection. It is opened when a new cartridge 52 is introduced into the device,

since, in this context, parts 116, 122, and 124 must be rotated relative to setting sleeve 151 so that plunger 108 can be brought into the correct position.

5 An axially displaceable coupling K6 is provided between protrusions 266, 268 of guide part 124 and rear adapter part 122. This coupling makes dose setting possible, as will be described below with reference to FIG. 23.

10 A slip coupling K7 is provided between front adapter part 116 and rear adapter part 122. It is described in more detail with reference to FIG. 14, and is formed by resilient catch 232 of front adapter part 116 and ratchet teeth 234 of rear adapter part 122. This slip coupling K7 becomes functional, if applicable, during cartridge replacement.

15 A force-dependent slip coupling K8 is provided between rear adapter part 122 and plunger 108. It is formed by micro-tooth set 162 (FIG. 8) of plunger 108 and the corresponding tooth set 250 (FIG. 14) on rear adapter part 122. It becomes functional in the course of an injection in order to make possible the expulsion of injection fluid 53 from cartridge 52, and also during replacement of a cartridge 52.

20 A torque-dependent coupling K9 is provided between cartridge holder 80 and front adapter part 116. It is formed by cutout 118 (FIG. 5) of external thread 114 and the radially inwardly projecting part 242 (FIG. 14) of front adapter part 116. This coupling K9 becomes functional when a cartridge 52 is replaced, and ensures that plunger 108 is brought into the correct position during cartridge replacement.

25 A position-dependent coupling K10 is provided between longitudinal ribs 111 of cartridge holder 80 and internal splines 112 of middle barrel part 48. Coupling K10 is engaged as long as injections are taking place, and prevents cartridge holder 80 from rotating relative to front adapter part 116 while injection needle 76 is being replaced. Coupling K10 is automatically opened during cartridge replacement, since cartridge holder 80 then needs to be 30 unscrewed from front adapter part 116.

The interaction of couplings K1 through K10 is evident from the description of the Figures below. For example, in FIG. 15 couplings K4 and K5 are closed and coupling K3 is open.

35 FIG. 19 once again shows injection device 30 in its position as shown in FIG. 3, but in a continuous longitudinal section. The labeling of the parts is the same as in the previous Figures, so that reference can be made thereto. It is evident that during cocking, protrusions 266, 268 make contact against

front adapter part 116, i.e. parts 124, 122, 116 are (after an injection) completely pushed together in telescoping fashion, just as in FIGS. 16 and 17. They can therefore transfer the cocking force of cocking cap 56 directly to spring 172 and compress the latter until latching element 64 snaps into latch 5 cutout 38.

Coupling K1 is open, i.e. dose setting is not possible.

Coupling K2 is open, i.e. plunger 108 is not releasably latched to part 150.

10 Coupling K3 is activated, i.e. latching element 184 is engaged into splines 220.

Coupling K4 is open, i.e. setting sleeve 151 is free to rotate.

Coupling K5 is closed, i.e. guide part 124 and rear adapter part 122 are not rotatable relative to barrel 36.

15 Coupling K8 is engaged, i.e. the two adapter parts 116, 122 must follow the axial movements of plunger 108.

Coupling K10 is engaged, i.e. longitudinal ribs 111 of cartridge holder 80 are guided by internal splines 112 of middle barrel part 48, and cartridge holder 80 is thereby prevented from rotating.

20 FIG. 20 shows substantially a plan view of the inner side of front adapter part 116 in its assembled state. For the sake of brevity, the reader is referred to the explanations of FIG. 14. Particularly evident is cutout 224, which is configured for engagement with the socket wrench-like end 120 (FIG. 5) of cartridge holder 80. Cutout 98 of cartridge holder 80 has a diameter which allows plunger 108 to slide through it.

25 FIG. 21 shows the manner in which parts 252, 254, and 268 engage interdigitally into one another. As already described, parts 266, 268 serve to join parts 122, 124 nonrotatably to one another but make them axially displaceable relative to one another, as is particularly clearly apparent from FIG. 6.

30 FIG. 22 shows the injection device in the position as shown in FIG. 2 and in longitudinal section. To prepare an injection, the patient has unscrewed cocking cap 56 (FIG. 2) from thread 60, and the cocked spring 172 has displaced the internal parts of the device approximately 2 mm in the proximal direction so that latching knob 64 is in contact against the proximal 35 end of cutout 38.

As a result, coupling K1 is now engaged, i.e. setting sleeve 151 can be rotated, by turning setting knob 32, in order to set the desired injection dose.

5            Coupling K3 is still in engagement, i.e. latching catch 184 is engaged into splines 220.

5            Coupling K4 is not engaged, i.e. the setting sleeve is rotatable relative to the barrel for dose setting.

5            Coupling K5 is engaged, i.e. guide part 124, rear adapter part 122, and plunger 108 cannot rotate relative to barrel 36.

10           Coupling K8 is engaged, i.e. rear adapter part 122 is coupled to plunger 108 and cartridge holder 80 in the axial direction as well, so that in the axial direction, these parts can move only together.

10           Coupling K10 is also engaged.

15           In this situation the proximal tip of injection needle 76 is at a spacing Z from the proximal end of barrel part 50. This is the maximum spacing, and setting a dose causes it to become smaller, as will be described below with reference to FIG. 23.

15           In FIG. 23, setting knob 32 is rotated clockwise (arrow 300 in FIG. 23) when viewed in the direction of an arrow 302, i.e. when viewed in the proximal direction.

20           Since coupling K1 is engaged, setting sleeve 151 - which is immobilized in its axial position by latching member 64 - is thereby rotated. With its internal thread 152, setting sleeve 151 screws plunger 108 in the proximal direction, since the latter is prevented from rotating by the engagement of part 160 of guide member 124.

25           Coupling K4 is open, i.e. setting sleeve 151 can rotate freely.

25           Coupling K5 is closed, i.e. guide member 124 and rear adapter part 122 are prevented from rotating relative to barrel part 36.

30           Upon displacement in the proximal direction, plunger 108 carries rear adapter part 124 along by way of coupling K8 (cf. description of FIG. 18). Said part 124 displaces front adapter part 116 that is joined to it, and with the latter cartridge holder 80, in the proximal direction over a distance Y that corresponds to the dose to be injected. The spacing between the proximal end of needle 76 and the proximal end of barrel part 50 is thereby decreased in FIG. 23 from Z (FIG. 22) to (Z - Y). Needle 76 is still not visible to the patient.

35           After the dose to be injected has been set, injection device 30 is then ready for an injection. The dose Y that was set remains stored, since coupling K3 prevents any rotation of setting sleeve 151.

For an injection, the patient places the device on the part of the body where an injection is to be performed, for example on the buttocks, and then, as shown in FIG. 24, presses with a symbolically indicated force  $F$  on clip 40 so that the latter is deflected inward and, with its protrusion 44, presses 5 latching knob 64 inward so that the cocked injection spring 172 displaces setting sleeve 151 in the proximal direction. In this context, latching knob 64 slides in axial longitudinal groove 136 (FIG. 6) of internal tube 130.

In this process, coupling K1 initially remains closed. Coupling K3 10 opens, since splines 220 slide out of latching element 184. During this sliding-out process, setting sleeve 151 slides with its external splines 222 (FIG. 13) into internal splines 134 (FIG. 6) of internal tube 130, and is thereby uninterruptedly prevented from rotating, so that the dose set by the patient remains stored without change. Setting sleeve 151 brings about, by way 15 of its internal thread 152, an axial displacement of plunger 108 in the proximal direction. Since the latter is joined via coupling K8 to rear adapter part 122, the latter, and with it front adapter part 116 and cartridge holder 80, is also moved in the axial direction so that (as shown in FIG. 24) needle 76 is inserted into the patient. This is therefore the operation by which needle 76 is inserted.

Coupling K5 remains closed in this context, i.e. guide member 124 cannot 20 rotate relative to barrel part 36. Guide part 124 is in direct drive connection with setting sleeve 151, so that guide member 124 is also displaced in the proximal direction, but cannot rotate and also (by way of its engagement member 160) prevents any rotation of plunger 108.

During the needle insertion operation, cartridge holder 80 is moved in 25 the proximal direction until its annular collar 100 strikes against damping ring 102, which is braced against annular shoulder 104. This terminates the movement of cartridge holder 80 in the proximal direction. Coupling K10 remains continuously engaged; in FIG. 24, internal splines 112 of middle 30 barrel part 48 are in engagement only with the distal end region of longitudinal ribs 111, as depicted in FIG. 24.

FIG. 25 shows the further progress of an injection. Since annular collar 100 has come to a stop against damping ring 102, cartridge holder 80 can move 35 no farther in the proximal direction, and coupling K8 is thereby disengaged, i.e. teeth 250 of part 248 (FIG. 14) now slide over micro-tooth set 162 (FIG. 8) of plunger 108 so that the latter is moved, independently of cartridge 40 holder 80, farther in the proximal direction, thereby displacing piston 106 in cartridge 52 over the distance  $Y$  that was set, and thus expelling from needle 76 the dose of medication 53 set by the patient, as indicated symbolically in FIG. 25 at 304.

During this movement, front adapter part 116 and rear adapter part 122

no longer change their axial position in barrel part 48, i.e. they remain stationary, while setting sleeve 151, and guide part 124 joined to it, continue to move over distance Y that was set. Since plunger 108 is axially joined to setting sleeve 151 by the latter's thread 152, plunger 108 also moves over distance Y in the proximal direction and displaces piston 106, since cartridge 52 cannot move any farther in the proximal direction.

5 During its axial movement, setting sleeve 151 slides with its external splines 198 out of internal splines 196 of setting knob 32, i.e. coupling K1 is opened. Torsion spring 190 can therefore turn setting knob 32 back into its 10 zero position, as symbolized in FIG. 25 by rotation arrow 310.

10 During the final phase of an injection, the inner parts of injection device 30 are thus pushed together, in telescoping fashion, a specific distance Y over which they had previously been moved apart from one another when the dose was set (FIG. 23).

15 Couplings K4 and K5 are, in this context, engaged. Coupling K8 is open during the final phase of an injection, but comes back into engagement immediately thereafter. Coupling K10 remains continuously engaged.

20 Coupling K5 is formed here by the fact that the distal end of external splines 274 (FIG. 6) of guide part 124 is in engagement with the proximal end region of internal splines 134. Plunger 108 is prevented from rotating by 25 guide part 124 (part 160 of guide part 124).

25 After the injection, the patient pulls needle 76 out of the tissue, replaces it with a new needle if applicable, and then screws on cocking cap 56, so that device 30 once again assumes the state shown in FIGS. 3 and 19. In this state the device can be transported, for example in a case or purse. If 30 insulin is to be injected with the device, refrigerated storage (in a refrigerator) is desirable.

35 When the contents 53 of a cartridge 52 are exhausted, the patient sees this through viewing window 54 (FIG. 5) or 54A (FIG. 34). As shown in FIG. 15, plunger 108 has stops 166, one of which (in this case) strikes against guide member 160 of guide part 124, thus preventing dose setting and indicating to the patient that he or she must now replace cartridge 52. In this situation the patient can administer only the remaining quantity of ingredient that is present in cartridge 52.

40 In the context of a cartridge replacement, FIG. 26 shows that proximal barrel part 50 is unscrewed from the uncocked injection device 30. This is symbolized in FIG. 26 by a rotation arrow 312.

45 Since stop 102, 104 now does not exist, front adapter part 116 is displaced, in response to the action of spring 172, until it comes to a stop 40 against the distal-side inner rim 314 (FIG. 5) of internal splines 112 of

middle barrel part 48. Coupling K5 thus opens, while coupling K4 remains engaged. Coupling K10 also opens, i.e. cartridge holder 80 can now be rotated relative to middle barrel part 48. Coupling K1 also remains open, i.e. it is not possible to set a dose.

5 FIG. 27 shows the injection device after proximal barrel part 50 has been unscrewed. As already explained, cartridge holder 80 can now be rotated in the direction of a rotation arrow 317, i.e. counterclockwise when viewed in the direction of an arrow 315.

10 Coupling K9 (FIG. 18) initially remains closed, i.e. resilient tongue 242 (FIG. 14) projects into cutout 118 (FIG. 5) of external thread 114. The rotational movement in the direction of arrow 317 is therefore transferred to front adapter part 116 and from it to rear adapter part 122 and guide part 124. The latter, by way of its engagement member 160, rotates plunger 108, since coupling K5 is open. Since coupling K4 is engaged, plunger 108 is 15 screwed in the distal direction in the direction of arrow 316. Teeth 250 of rear adapter part 122 thus slide (FIG. 14) over micro-tooth set 162 (FIG. 8) of plunger 108. The latter is screwed in the distal direction until its stop 318 strikes against engagement member 160 of guide part 124. This state is depicted in FIG. 28.

20 Plunger 108 now can move no farther in the distal direction and parts 116, 122, and 124 consequently can no longer rotate, so that coupling K9 is now disengaged and cartridge holder 80 is unscrewed from front adapter part 116.

25 This state is shown in FIGS. 28 and 29. Plunger 108 is parked in the interior of barrel 36, 48, and its distal end 168 is in latching engagement, by way of annular groove 170 thereon, with a radially inwardly projecting collar 322 of part 150. In this state latching coupling K2 is thus engaged, and immobilizes plunger 108.

30 As shown in FIG. 30, empty cartridge 52 is now removed from the unscrewed cartridge holder 80; and as shown in FIG. 31, a full cartridge 52 is inserted into cartridge holder 80.

35 As shown in FIG. 32, cartridge holder 80 with the new cartridge 52 is screwed back onto front adapter part 116. Viewed in the distal direction 315, cartridge holder 80 is rotated clockwise for this purpose. Since latching coupling K2 as shown in FIG. 29 is closed, plunger 108 initially cannot move in the proximal direction; as a result, any rotational movement of guide part 124, rear adapter part 122, and front adapter part 116 is also blocked, so that cartridge holder 80 is screwed completely into front adapter part 116 until latching coupling K9 comes into engagement there. Only then is latching 40 coupling K2 disengaged by the torque exerted by the user, and plunger 108 is displaced in the proximal direction until it comes to rest gently against piston 106.

Since cartridge 52 is sealed in fluid-tight fashion, piston 106 cannot be displaced in it. If the user tries to use force to keep turning cartridge holder 80 in the direction of rotation arrow 321 (FIG. 32), coupling K7 takes effect, i.e. latching catch 232 (FIG. 14) slides over ratchet teeth 234. In 5 this situation the user therefore cannot damage injection device 30 even by using force, since if a predefined torque in this rotation direction is exceeded, the effect of coupling K7 is to allow front adapter part 116 to rotate freely relative to rear adapter part 122. Coupling K7 therefore acts, in the direction just described, as a slip coupling. This is not necessary in 10 the opposite direction, since in this direction cartridge holder 80 is unscrewed from front adapter part 116.

Slip coupling K7 prevents the patient from elastically compressing rubber piston 106 by exerting too much torque. The consequence of this would be that in FIG. 33, after needle 76 (FIG. 3) is screwed on, injection fluid 53 15 would spray out of said needle, which is undesirable. Coupling K7 prevents this.

As shown in FIG. 33, proximal barrel part 50 is now also screwed on (rotation arrow 324); coupling K10 is thereby closed, and injection device 30 is then in a position analogous to FIG. 25 and is once again completely ready to use, i.e. no further adjustment or testing operations are necessary. If air bubbles should be present in cartridge 52, these can be removed by spraying a small injection dose upward into the air. This is demonstrated to the patient during instruction at the hospital.

Screwing on barrel part 50 causes cartridge holder 80 to be displaced in the distal direction, because annular collar 104 of barrel part 50 displaces annular ridge 100 of cartridge holder 80 in the distal direction. Coupling K10 comes into engagement, and cartridge holder 80 is once again guided, with its longitudinal ribs 11, nonrotatably in splines 112 (FIG. 5). Coupling K5 also comes back into engagement, and coupling K4 remains engaged, blocking any displacement of plunger 108. Coupling K1 remains disengaged, so that dose setting is deactivated. In this position, the patient therefore cannot influence the position of plunger 108 if he or she plays around with the device. Coupling K3 is not engaged in this position. Parts 124, 122, 116 are still pushed together in telescoping fashion.

35 After an injection needle 76 is put in place, the device can be cocked by screwing in cocking cap 56 and is then in a transportable state.

FIG. 34 shows a variant in which a plurality of small holes 54A are used as the viewing window. This is the preferred approach in the context of the 40 invention, since the patient cannot reach through said holes 54A and therefore cannot slow down an injection procedure with his or her fingers.

FIG. 35 shows the injection device of FIG. 34 from above, but at a larger scale than FIG. 34.

FIG. 36 schematically depicts splines 220 of setting sleeve 151 (FIG. 7) and latching member 184 (FIG. 8) which engages resiliently, during dose setting, into said splines 220. The dose settings from zero to "58" are indicated by way of example.

Splines 220 have a total of thirty-two teeth 221, so that the angle ( $\mu$ ) between two adjacent teeth is  $360^\circ/32 = 11.5^\circ$ . Because of stop 75 (FIG. 9), two teeth are not used for dose setting.

This number of thirty-two teeth is used in the same fashion in spline sets 112, 134, 196, 198, 220, 222, 256, and 274, so that the parts of injection device 30 can easily slide into and out of one another. For this reason, these spline sets therefore also have the same angular position relative to one another, i.e. no "phase shift."

Note also the following with regard to operation: the distance L (FIGS. 25 and 39) that latching member 64 travels after it is triggered during an injection is always the same.

Insertion depth U (FIG. 25) of needle 76 also remains unchanged in normal circumstances. (An insertion depth adjustment can, of course, be used in order to adapt the insertion depth to the patient.)

What is different in the context of distance L is the portion Y that is used for the displacement of piston 106. This portion Y is defined before the injection, by the fact that parts 124 and 122 are moved that distance Y apart during dose setting (cf. FIG. 23), thus causing needle 76, even before the injection, to be displaced that distance Y in the proximal direction. The distance traveled by needle 76 during an injection is therefore shorter than L by an amount equivalent to distance Y, as explained with reference to FIGS. 22 and 23.

As will be explained below with reference to FIGS. 39 and 40, internal splines 134 (FIG. 6) have a length of approximately L, since they must prevent guide part 124 from rotating during the entire travel length L. At the end of an injection, guide part 124 is still, with the distal end of its splines 274, just in engagement with internal splines 134, as FIGS. 25 and 39 show; and before an injection begins, the situation (as shown in FIGS. 22 and 28) is that splines 222 of setting sleeve 151 are just about to engage with internal splines 134, for which reason splines 274 of the immediately adjacent guide part 124 are fully engaged with internal splines 134 (cf. FIGS. 22 and 38).

The result is to yield an injection device that is physically short and functions very reliably, and to simplify replacement of a cartridge 52.

FIG. 37 once again illustrates the couplings that become active during cartridge replacement.

Located between container 80 and front adapter part 116 is a disengageable connection (external thread 114, internal thread 115) that could, if applicable, also be configured as a bayonet closure or the like.

Coupling K9 (parts 118, 242) is located in this disengageable connection. When container 80 is opened, K9 causes plunger 108 to be displaced into the latched position as shown in FIG. 29.

Coupling K7 (latching member 232 - visible in FIG. 14 - and ratchet teeth 234) is located between front adapter part 116 and rear adapter part 122. When container 80 is closed, coupling K7 ensures that plunger 108 is brought only gently into contact against piston 106, and does not elastically deform it.

Coupling K6 (protrusions 266, 268 and cutouts 270, 272) is located between rear adapter part 122 and guide part 124. It allows adjustment of the axial spacing between parts 122, 124, and transfer of a torque between them.

Couplings K7 and K9 can optionally be combined, for example if a bayonet closure is used (instead of threads 114, 115) for container 80.

If coupling K9 is defective, the user can use proximal end 120 of container 80 as a socket wrench to turn front adapter part 116 by engaging into its part 226.

FIGS. 38 through 40 synoptically show various possible positions of couplings K4 and K5.

In FIG. 38, the device is cocked and - at a dose setting of zero - ready to be triggered. Coupling K4 is not engaged. Coupling K5 is engaged. The boundary between setting sleeve 151 and guide part 124 is located at point A, namely at the distal end of internal splines 134.

In FIG. 39, the injection is complete. Latching member 64 has traveled distance L. The boundary between parts 151 and 124 has moved to point B, which is at a spacing L from point A. Point B is located above the lower end of splines 134, i.e. the latter are longer than L so that in FIG. 39, coupling K5 can remain closed, i.e. the distal part of splines 274 remains in engagement with internal splines 134. Coupling K4 is engaged during the injection.

FIG. 40 shows the situation during cartridge replacement. The aforesaid boundary between parts 151 and 124 has shifted to point C. Coupling K4 is still closed, i.e. part 151 cannot rotate, and coupling K5 is open so that guide part 124 can be rotated during cartridge replacement, as already described in detail. The spacing between A and C corresponds approximately to the axial length of internal splines 134, and is greater than L.

Instead of the couplings depicted, other types of coupling can also be used, for example couplings that utilize magnets. If the device is, for example, controlled by a microprocessor or microcontroller, couplings can be actuated by electrical energy.

Many other variations and modifications are, of course, possible within the context of the present invention.